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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,001	08/26/2003	Casey K. Lee	SPINE 3.0-429	3316
530	7590	02/04/2008	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			SHAFFER, RICHARD R	
		ART UNIT	PAPER NUMBER	
		3733		
		MAIL DATE	DELIVERY MODE	
		02/04/2008	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/648,001

**Applicant(s)**

LEE, CASEY K.

**Examiner**

Richard Shaffer

**Art Unit**

3733

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 11 January 2008.  
2a) This action is **FINAL**.      2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 26,31-36 and 38 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 26,31-36 and 38 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
    1. Certified copies of the priority documents have been received.  
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_\_  
5) Notice of Informal Patent Application  
6) Other: \_\_\_\_\_

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 11th, 2008 has been entered.

### ***Specification***

The amendment to the abstract filed on January 11<sup>th</sup>, 2008 is acknowledged and accepted by the examiner. The previous objection to the abstract is hereby withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 31-36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al (US Patent Application Publication 2002/0016633).

Lin et al disclose making (Column 2, Paragraph 0032 and 0033) an intervertebral spacer from bone harvested from the calcaneus with various configurations such as square, rectangular, angled, circular, hexagonal, and a trailing end having angled walls (22). Lin et al specifically discuss making horizontal cuts across

the metaphysics of a long bone such that anatomical loading for the spacer is the same as the donor location. Therefore, about 98% of each cut would be cancellous bone with a thin layer of cortical bone surrounding the cancellous bone. The bone as long as it is healthy (as it should be, otherwise it would not be selected as donor bone) would be able to support 1000 pounds. Therefore, Lin et al disclose cutting a portion of the calcaneus into two or more subsections (each cross-sectional piece). Each piece having a thin layer of cortical bone formed integral and partially surrounding a core of cancellous bone.

Lin et al fail to disclose how a cut would specifically be made in the calcaneus from a donor and therefore is silent whether the cut is perpendicular to the long axis of the calcaneus. Applicant has not stated any unexpected result or benefit of performing cross-sectional cuts perpendicular to the long axis of the calcaneus and actually states that such is not the only possible direction for cutting. It would have been obvious to one having ordinary skill in the art to consider making cross-sectional cuts either perpendicular to the long axis of the calcaneus or perpendicular to the axial loading axis as a matter of mere preference with no unforeseen benefits or results.

It would have been further been obvious to extract the calcaneal bone from a living donor of similar genetic composition in cases where the subjects own bone would be detrimental (severe arthritis, cancer, osteoporosis, general bone disease) while reducing the likelihood of tissue rejection by the subject's immune system as well as reducing additional trauma to the patient if bone was acquired from a deceased individual.

***Response to Arguments***

Applicant's arguments filed January 11<sup>th</sup>, 2008 have been fully considered but they are not persuasive. Applicant states that Lin et al merely disclose a spacer that may include cancellous calcaneus bone by comparing paragraphs 0032 and 0042 where the cortical u-shaped insert fails to include the calcaneus as a donor site.

This is irrelevant to the previous rejection and the current rejection. As clearly shown in Figure 1B of Lin et al, a horizontal cut forming a cross-section of cancellous and cortical bone from a long bone is shown to which bone blocks are cut out of. Therefore, since Lin et al disclose and teach that the calcaneus is also an acceptable and equivalent donor site (at least for cancellous bone due to the omission with regard cortical in paragraph 0042), that one would still be taught to make complete cross-sectional cuts through a portion of the calcaneus. These cross-sections all come from a "portion" of the calcaneus, thereby having the portion of the calcaneus cut to provide at least two subsections, with each implant including a thin layer of cortical calcaneus bone surrounding the cancellous calcaneus bone. The interpretation of Line et al relies upon an intermediate product in the method, not the final product where the cancellous bone was removed from the cross-sectional cut and later placed within a separate cortical shell.

***Conclusion***

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the

application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

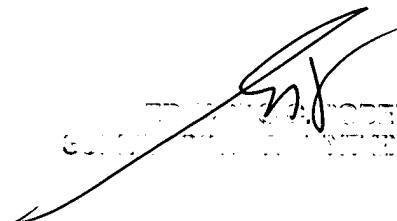
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Richard Shaffer*

Richard Shaffer  
February 1<sup>st</sup>, 2008



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